

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 120201	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/AU2004/001348	International filing date (<i>day/month/year</i>) 30 September 2004	Priority date (<i>day/month/year</i>) 1 October 2003	
International Patent Classification (IPC) or national classification and IPC Int. Cl. G01N 33/483 (2006.01) H01J 49/40 (2006.01)			
Applicant PROTEOME SYSTEMS INTELLECTUAL PROPERTY PTY LTD et al			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of 5 sheets, as follows:</p> <div style="margin-left: 40px;"> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> </div> <p style="margin-left: 20px;">b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																									
<p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>		<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
<input checked="" type="checkbox"/>	Box No. I	Basis of the report																							
<input type="checkbox"/>	Box No. II	Priority																							
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability																							
<input type="checkbox"/>	Box No. IV	Lack of unity of invention																							
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																							
<input type="checkbox"/>	Box No. VI	Certain documents cited																							
<input type="checkbox"/>	Box No. VII	Certain defects in the international application																							
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																							

Date of submission of the demand 20 July 2005	Date of completion of this report 13 January 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer ROSS OSBORNE Telephone No. (02) 6283 2404

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001348

Box No. I Basis of the report

1. With regard to the language, this report is based on:
 - ☒ The international application in the language in which it was filed
 - ☐ A translation of the international application into _____, which is the language of a
 - ☐ international search (under Rules 12.3(a) and 23.1 (b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
 - ☐ the international application as originally filed/furnished
 - ☒ the description:
 - pages 1, 3-5, 7-12 as originally filed/furnished
 - pages* 2, 2a, 6 received by this Authority on 20 July 2005 with the letter of 20 July 2005
 - pages* received by this Authority on with the letter of
 - ☒ the claims:
 - pages as originally filed/furnished
 - pages* as amended (together with any statement) under Article 19
 - pages* 13-14 received by this Authority on 20 July 2005 with the letter of 20 July 2005
 - pages* received by this Authority on with the letter of
 - ☒ the drawings:
 - pages 1/5-5/5 as originally filed/furnished
 - pages* received by this Authority on with the letter of
 - pages* received by this Authority on with the letter of
 - ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to the sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-9	YES
	Claims	NO
Inventive step (IS)	Claims	YES
	Claims 1-9	NO
Industrial applicability (IA)	Claims 1-9	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

D1 - WO 2001/096861

D2 - US 6489608

D3 - Cooper C. et al, "GlycoSuiteDB: a new curated relational database of glycoprotein glycan structures..."

D4 - US 6393367

NOVELTY (N) Claims 1-9

None of the citations disclose a method of assigning the probable composition of a glycan by a method involving use of monosaccharide frequencies from a reference set or database, or uses the particular statistical methods disclosed for this purpose. The claims are therefore novel.

INVENTIVE STEP (IS) Claims 1-9

The problem addressed by the current application is find an improved method of glycan analysis for ranking possible saccharide compositions identified as being consistent with a given mass or mass range associated with an uncharacterized glycan of interest.

The applicant's solution is to take into account the probability that a particular saccharide will be present using frequency information calculated from known glycan populations available in databases such as 'glycosuite' and use a scoring system to rank the possible glycan saccharide compositions on a probability basis.

Similar but more complex methods have been devised in the prior art, primarily for analysing proteins. These are not fully applicable to glycan analysis because of the differences in subunit structures and crosslinking.

However faced with the problem of ranking possible glycan structures produced using the well known and commonly used platforms such as glycosuite and glycomed, the skilled addressee prior art would naturally look to adapt approaches used in ranking possible structures that have been used with biological molecules. Documents such as D1, D2 and D4, teach that the use of frequencies scores, subpopulations and likelihood factors to rank possibilities is known. D4 which even generally envisages that its approach can be used for carbohydrates, describes methods of analysing data involving determining the probability that a biological molecule identification is correct and calculating a score for the comparison, generating an artificial data set and calculating sample and population means and standard deviations. From these combined teachings it would appear that an approach has been taken consistent with what has been effected with proteins in the prior art. Similarities include the use of an artificial data set equating with the approach of the claimed reference group and the use of sample and population means and likelihood factors is in general terms equating with the claimed use of a mean and standard deviation for each component and partial scores

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

The applicant is thus using the general approaches taught by the prior art for proteins etc with the glycan databases and programs such as glycosuite and glycomed to achieve a ranking result that, while more limited than what has been achieved with proteins and peptides is still useful. However this adaptation of some of the basic ideas used for the protein work appears routine in concept and implementation and does not appear to provide a basis for an inventive step. In the light of D1, D2 and D4, it would be obvious to the person skilled in the art when faced with the problem of improving the sorting of possible saccharide compositions that exist for a given mass, to utilise saccharide frequencies as can be found from D3 and score them so as to identify the more probable compositions.

The particular statistical equations defined in claims 4-6 to assist the ranking of possibilities appear to be routine variations of those considered in D1 or D2 and have no unexpected benefits over the use of the statistical means already envisaged in the prior art. A similar equation to that defined in claim 4 is disclosed in D4 (see column 12 line 14-19) for measuring likelihoods and there seems no inventive step in using this measure for ranking approach of D1 or D2. Likewise, none of the other appended claims contain features that would lead to an inventive step. For these reasons all claims lack an inventive step.